

REMARKS

These remarks are in response to the Non-Final Office Action mailed February 3, 2009. Claims 3-4 have been canceled without prejudice to Applicants' right to prosecute the canceled subject matter in any divisional, continuation, continuation-in-part or other application. Claim 1 has been amended. Support for the amendments to claim 1 can be found in claims 3-4 and previously pending. Claims 5 and 7 have been amended to correct dependencies. No new matter is believed to have been introduced.

I. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-5, 7 and 8 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. The claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office alleges that there is no support for "function other than . . . a CKI sequestration activity" in paragraphs 60 and 202. Claim 1 has been amended and claims 3 and 4 cancelled. Applicants believe that the rejection is moot.

For at least the foregoing reasons, Applicants respectfully request withdrawal of this rejection.

II. REJECTION UNDER 35 U.S.C. §102

Claims 1-2 and 7-8 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Hybridon (WO 99/27087). Applicants respectfully traverse this rejection.

In order for a reference to anticipate the claimed invention each and every element of the invention must be found in the prior art reference.

Hybridon does not mention, teach or suggest CDK1. Moreover, Hybridon do not teach or suggest the method as set forth in claim 1 wherein the ratio of the levels of CDK1 and CDK4 gene products are in the range of 0.6 to 1.6, or that an effective agent is identified as an agent capable of altering the ratio of CDK1 and CDK4.

Accordingly, Hybridon cannot anticipate Applicants' claimed invention because Hybridon do not teach or suggest each and every element of Applicants' claims.

Claims 1 and 2 stand rejected under §102(b) as allegedly anticipated by Chen et al. (USP 6,004,939). Applicants respectfully traverse this rejection.

Chen et al. disclose a method for screening for compounds that inhibit telomerase activity. Chen et al. do not teach or suggest a method of screening for an agent effective in the treatment of cancer comprising determining whether an agent has altered the ratio of CDK1 and CDK4. Accordingly, Chen et al. cannot anticipate Applicants' claimed invention because Chen et al. do not teach or suggest each and every element of Applicants' claims.

Thus, neither Hybridon nor Chen et al. teach or suggest each and every element of Applicants' claimed invention. According, Applicants respectfully request withdrawal of the rejection.

III. REJECTION UNDER 35 U.S.C. §103

Claims 1 and 3-5 stands rejected under 35 U.S.C. §103 as allegedly unpatentably over Hybridon, as applied above, in view of Theryte Ltd. (WO 99/42821). Applicants respectfully traverse this rejection.

Hybridon, the primary reference, is discussed above and does not teach or suggest the elements of Applicants claimed invention, let alone the method as a whole. To overcome the deficiencies of the primary reference, the Office combines Theryte Ltd. with Hybridon.

Theryte Ltd. do not teach and suggest all the elements of the claimed invention. The Office directs the Applicants to Figure 5 in support of the contention that the ratio of CDK4 to CDK1 is approximately 1 in cancer cells. However, the construction given to Figure 5 by the Office can only be justified by hindsight, particularly in view of what the Theryte Ltd. reference actually teaches and suggests. Figure 5 would have taught the skilled person that there is a correlation between CDK1 and CDK4 levels in P53 to mutant human cancer cells (see the description of Figure 5 on page 4 of Theryte); however, this description and the figure itself would

not have led the skilled person to investigate the importance of the *ratio* of these two gene products. For example, nowhere in Theryte is the skilled person taught (nor is it suggested) that a cancer cell sample can be identified as one which consists of one or more cells in which the ratio of the levels of the CDK1 and CDK4 gene products is in the range of 0.6 to 1.6. What can be gleaned (*i.e.*, what is actually taught and suggested by Theryte) is that a cancerous state can be identified simply by testing a sample for the elevation of CDK1 and CDK4 (see claim 1 of Theryte). It is submitted that there is no mention anywhere in Theryte of the importance of the ratio of CDK1 to CDK4. More particularly, there is nothing in the Theryte application that teach or suggest screening for an agent to treat cancer by examining the ratio of CDK1 to CDK4 when determining the effectiveness of an putative cancer treating agent.

For, at least, the foregoing reasons the claims submitted herewith are non-obvious over the references either alone or in combination.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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